

Report to Congress

**Performance Evaluation of Accreditation Bodies
under the
Mammography Quality Standards Act of 1992
as amended by the
Mammography Quality Standards Reauthorization Acts
of 1998 and 2004**

January 1, 2011 to December 31, 2011

U.S. Department of Health and Human Services

Food and Drug Administration

/s/

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Date _____

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Commissioner of Food and Drugs

Executive Summary

The goal of the Mammography Quality Standards Act (MQSA) of 1992, as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004, is to assure that facilities meet standards for performing high quality mammography. The Food and Drug Administration (FDA) administers the MQSA. Among other things, the MQSA provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities based upon quality standards. Only facilities that are accredited by ABs, or undergoing accreditation by ABs, may receive certificates from the FDA (or an FDA-approved state certifying agency or private nonprofit organization) to legally perform mammography. The MQSA requires annual reports to Congress on AB performance. This sixteenth annual report covers the period from January 1, 2011 through December 31, 2011.

To implement the MQSA (Section 354q of the Public Health Service Act, (42 United States Code (U.S.C.) 263b)), FDA issued final regulations that became effective on April 28, 1999 (21 Code of Federal Regulations (CFR) Part 900). The final regulations (21 CFR 900.5) require that the FDA's evaluation of ABs shall include a(n):

- (a) Assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the AB or other sources or has been required by FDA as part of its oversight initiatives; and
- (b) Determination of whether there are major deficiencies in the AB's performance that, if not corrected, would warrant withdrawal of the approval of the AB under the provisions of Section 900.6.

Status of Accreditation Bodies

Currently, there are four ABs: the American College of Radiology (ACR), a private nonprofit organization, and the state ABs of Arkansas (SAR), Iowa (SIA), and Texas (STX). FDA renewed its approval of each of the ABs under the MQSA regulations in 2005. The terms of approval are for a period of seven years. Although the expiration for renewal is April 28, 2013, FDA will continue to annually review each AB's performance to determine its compliance with the MQSA regulations.

Evaluation of Accreditation Bodies

To assess overall performance, FDA evaluates ABs in the following areas:

- resource analysis (staffing, funding, information technology capability);
- data management (process/errors);
- reporting and record keeping processes (serious consumer complaint and appeal mechanisms);

- accreditation review and decision making processes (clinical image review, phantom image review, equipment requirements);
- AB onsite visits to facilities (random and for-cause visits);
- random clinical image reviews of facilities (RCIRs);
- additional mammography reviews (AMRs);
- accreditation revocations and suspensions; and
- quantitative accreditation and inspection information.

FDA evaluates AB performance in the areas listed above through:

- examination of the ABs' responses to FDA questionnaires that address the performance areas;
- analysis of quantitative accreditation and inspection information;
- review of selected accreditation files, as well as clinical and phantom images;
- interviews with AB staff and management to answer questions or clarify issues;
- analysis of information from FDA's Mammography Program Reporting and Information System;
- onsite visits to the ABs; and
- ongoing written and oral communications with the ABs throughout the year.

Findings from Calendar Year (CY) 2011 AB Performance Evaluations

The following items are the highlights of FDA's CY 2011 Report to Congress:

- All ABs adequately funded their respective programs.
- All ABs took appropriate measures to secure and maintain their accreditation data.
- Each AB administered a satisfactory serious consumer complaint process.
- Each AB used acceptable procedures to review clinical images submitted by facilities, and has adequate audit procedures for its clinical image reviewers.
- All ABs used acceptable procedures to review phantom images submitted by facilities, and have adequate audit procedures for their clinical image reviewers.
- All ABs met or exceeded the required number of annual onsite visits to facilities they accredit.
- Each AB exceeded the required number of random clinical image reviews of the facilities it accredits.
- The ABs performed AMRs when indicated.
- One AB revoked the accreditation of three facilities in CY 2011.
- Facilities' phantom image scores showed no significant differences across the ABs and these scores improved from those reported in 2010.
- Overall, the rates for units denied accreditation remained about the same as those in the last reporting period.
- The average radiation dose (those measured by the facility medical physicists) for three ABs decreased from those previously reported and there was a non-

significant increase for one AB. All ABs remain well below the dose limit mandated by the MQSA final regulations.

- Eighty-three percent of accredited mammography facilities had no violations of the MQSA. This percentage is an increase from 82 percent reported in 2010.
- Only 0.5 percent of facilities had a violation characterized as “most serious.” This percentage is an improvement from the 0.7 percent reported in 2010. FDA actively works with these facilities on corrective measures, and takes regulatory actions as indicated.

FDA and ABs, working in partnership with the certified mammography facilities in the United States, and with the states participating in inspections and other MQSA activities, are ensuring quality mammography across the nation.

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I. Purpose

The Mammography Quality Standards Act (MQSA) of 1992 (P. L. 102-539), as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (P. L. 105-248 and P. L. 108-365), authorizes the Food and Drug Administration (FDA) to assure that facilities meet standards for performing high-quality mammography. FDA administers the MQSA. Among other things, the MQSA provides for FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities based on quality standards. FDA may approve either private nonprofit organizations or state agencies to serve as ABs. The MQSA also requires FDA to submit an annual performance evaluation of the approved ABs to the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce under 42 U.S.C. 263b(e)(6). This report covers the performance of the ABs under the MQSA from January 1, 2011 through December 31, 2011.

II. Status of Accreditation Body Approvals

Currently, there are four ABs: the American College of Radiology (ACR), a private nonprofit organization; and the state ABs of Arkansas (SAR), Iowa (SIA), and Texas (STX). The terms of approval of each AB under the MQSA regulations are for a period of 7 years. Currently, all ABs are approved until April 28, 2013. FDA will annually review each AB's performance to determine its compliance with the MQSA regulations.

III. Standards

Under the MQSA, each AB must require facilities it accredits to meet standards that are equal to the quality standards established by FDA under 42 U.S.C. 263b(f) to assure the safety and accuracy of mammography. All ABs have either adopted the MQSA standards by reference or have developed standards that are equal to the quality standards established by FDA. Each AB incorporated the standards into its own accreditation processes.

IV. Methodology

As outlined in MQSA regulations, FDA evaluates the ABs in the following areas:

- resource analysis;
- data management;
- reporting and record keeping processes;
- accreditation review and decision-making processes;
- AB onsite visits to facilities;
- random Clinical Image Reviews (RCIRs) of facilities;
- additional Mammography Reviews (AMRs);
- accreditation revocations and suspensions; and
- quantitative accreditation and inspection information.

FDA evaluates performance in these areas through:

- examination of the AB responses to questionnaires developed by FDA addressing performance indicators;
- analysis of quantitative accreditation and inspection information;
- review of selected accreditation files (including clinical and phantom images);
- interviews with AB staff and management to answer questions or clarify issues;
- analysis of information from FDA's Mammography Program Reporting and Information System database of annual facility inspections;
- onsite visits to the ABs; and
- ongoing written and oral communication with the ABs throughout the year.

FDA staff analyze unit accreditation pass and fail data, along with data that describe the reasons for each accreditation failure decision. Significant differences in pass and fail rates or reasons for accreditation denial among ABs could, for example, indicate that one AB is interpreting the significance of a particular quality standard more or less strictly than another.

To complement the information submitted by the ABs, MQSA inspectors assess accredited facility performance during inspections by collecting average radiation dose values and by measuring average phantom image scores and average processor speeds. Collectively, these measures reflect the overall functioning of all components of the mammography system.

V. Performance Indicators

A. Administrative Resources and Funding

AB staffs generally include managers, mammography radiologic technologists, MQSA inspectors, health physicists, information technology program application specialists, and administrative assistants. In 2011, all ABs continued to maintain adequate funding and staffing for their respective programs.

B. Data Management

All ABs provide FDA with electronic transmissions of accreditation data in a secure, timely, and appropriately maintained manner.

C. Reporting and Recordkeeping

FDA's review of the ABs' reporting and recordkeeping practices includes examining procedures for handling serious consumer complaints and appeals of accreditation decisions, as well as a procedure for granting interim accreditation.

1. Serious Consumer Complaints

The regulations require ABs to develop and administer a consumer complaint mechanism whereby all facilities that an AB accredits must file serious unresolved complaints with their AB. By regulation, each AB must submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them.

In CY 2011, ACR was the only AB that received complaints.. ACR investigated serious complaints from eight consumers. The AB submitted its serious consumer complaint report to FDA which indicated that the AB followed its approved procedures when resolving the complaints.

2. Appeals

Each AB must have a process for facilities to appeal an adverse accreditation decision. In CY 2011, ACR was the only AB that received appeals. The ACR handled the three appeals according to its FDA-approved procedures.

3. Interim Accreditation

An AB may grant a 45-day interim accreditation to a fully accredited facility whose MQSA certificate will expire prior to the AB making a renewal decision. The facility must be fully accredited and meet certain criteria in order to obtain interim accreditation at the time of accreditation renewal. Once the AB grants the facility interim accreditation, FDA (or an FDA-approved state certifying agency) may grant the facility a 45-day interim certificate.

In CY 2011, ACR granted interim accreditation to five of its facilities, SIA granted interim accreditation to one facility, and STX granted interim accreditation to three of its facilities. Each AB followed its approved procedure for granting interim accreditation.

D. Accreditation Review and Decision-Making Processes

Review of the ABs' accreditation and decision-making processes includes evaluating procedures for clinical image review, phantom image review, and mammography equipment evaluation and medical physicist annual survey review.

1. Clinical Image Review (CIR)

As part of the accreditation process, mammography facilities must submit clinical images, mammograms, to their ABs for review. To evaluate the ABs' performance in the clinical image review area, FDA's interpreting physicians (IPs) annually review clinical images from a sample of facilities that submit cases to the ABs for accreditation purposes. Generally, two FDA IPs independently conduct clinical image reviews of

images from each facility in the sample and for each of the ABs that perform clinical image review. Each examination is evaluated on the eight attributes listed in the MQSA regulations. ACR, SAR, and SIA have their own clinical image reviewers to evaluate their facilities' clinical images. ACR performs the clinical image reviews for STX under contract.

As part of FDA's continuing oversight of the three CIR programs, one of FDA's interpreting physicians will participate in each AB's next CIR training session to ensure that the attributes used to evaluate clinical image quality are consistently applied across the ABs. These training sessions will also serve as a venue to discuss any issues identified during FDA's oversight reviews.

Below is a summary of the results of FDA's clinical image reviews.

ACR AB

FDA performed its evaluation of ACR's clinical image review process in November 2011. In reviewing the clinical images and summary evaluation forms, FDA agreed with the final overall assessments (pass and fail) in all of the cases reviewed. FDA determined that this review of cases indicates that the quality of clinical image review by ACR remains high and has not deviated from past performance. In general, the clinical image reviewers are providing adequate feedback to facilities on ways to improve image quality.

SAR AB

FDA performed its evaluation of SAR's clinical image review process in August 2011. In reviewing the clinical images and summary evaluation forms, FDA agreed with the final overall assessments (pass and fail) in all of the cases reviewed. FDA determined that this review of cases indicates that the quality of clinical image review by SAR remains high and has not deviated from past performance. In general, the clinical image reviewers are providing adequate feedback to facilities on ways to improve image quality.

SIA AB

FDA performed its evaluation of SIA's clinical image review process in October 2011. In reviewing the clinical images and summary evaluation forms, FDA agreed with the final overall assessments (pass and fail) in all of the cases reviewed. FDA determined that this review of cases indicates that the quality of clinical image review by SIA remains high and has not deviated from past performance. In general, the clinical image reviewers are providing adequate feedback to facilities on ways to improve image quality.

Summary of Audits and Training of Clinical Image Reviewers by the ABs

Audits

An audit of clinical image reviewers ensures uniformity, identifies any potential problems, and provides all individual clinical image reviewers with the necessary data to compare his/her results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2011, ACR, SAR, and SIA conducted audits of their clinical image reviewers to collect statistics on reviewer agreement and non-agreement rates. The ABs use these rates to identify performance issues that may require corrective action. All reviewers with performance issues completed remedial action by attending a refresher course or by reviewing clinical image review protocols and guides. In CY 2011, five reviewers (5 percent of the total number of AB clinical image reviewers) required remediation.

Training

ACR, SAR, and SIA have clinical image review quality control activities that promote consistency among the various clinical image reviewers. The ABs conduct training sessions at which clinical image reviewers evaluate clinical images and discuss findings, including the application of AB clinical image review evaluation criteria. STX does not conduct training, because the clinical image reviewers for STX are provided by ACR under contract and participate in ACR's training program and quality control activities.

2. Phantom Image Review (PIR)

A phantom is a test object used to simulate radiographic characteristics of compressed breast tissue and contains components that radiographically model aspects of breast disease and cancer. As part of the accreditation process, mammography facilities must submit phantom images to its ABs for review. To evaluate the ABs' performance in the phantom image review area, FDA's MQSA expert staff annually review phantom images from facilities that submit cases to the ABs. Two FDA staff, working independently, review randomly selected phantom images from each AB. A third reviewer is used when there is a need for a tie-breaker. The FDA reviewers evaluate all test objects (fibers, specks, masses) on these images to determine whether they agree or disagree with the AB's pass/fail decisions. Below is a summary of the results of FDA's phantom image reviews.

ACR AB

FDA reviewed ACR's phantom images in November 2011. FDA reviewers agreed with ACR's scores in all cases and determined that the quality of the phantom image review performed by ACR remains high and has not deviated from past performance.

SAR AB

FDA reviewed SAR's phantom images in September 2011. FDA reviewers agreed with SAR's pass/fail assessment in nine out of ten cases reviewed. FDA accepts some variability in reviewer agreement when the image is a borderline case, as happened with this case where three reviewers passed the image and two failed it. FDA concluded that the quality of the phantom image review performed by SAR remains high and has not deviated from past performance.

SIA AB

FDA reviewed SIA's phantom images in October 2011. FDA reviewers agreed with SIA's pass/fail assessment in all of the cases reviewed. FDA concluded that the quality of the phantom image review performed by SIA remains high and has not deviated from past performance.

STX AB

FDA reviewed STX AB's phantom images in August 2011. FDA reviewers agreed with STX's pass/fail assessment in all of the cases reviewed. FDA concluded that the quality of the phantom image review performed by STX AB remains high. STX AB has satisfactorily addressed concerns identified in the 2010 Report.

Summary of Audits and Training of Phantom Image Reviewers by ABs

Audits

An audit of phantom image reviewers ensures uniformity, identifies any potential problems, and provides all phantom image reviewers with the necessary data to compare their results to the rest of the review group. ABs use audit results to enhance reviewer training by emphasizing any performance issues. In 2011, each AB conducted audits of its phantom image reviewers to collect statistics on reviewer agreement and nonagreement rates. The ABs use these rates to identify performance issues that may require corrective action. All reviewers with performance issues completed remedial action by attending a refresher course or reviewing phantom image review protocols and guides. In CY 2011, one reviewer (1.9 percent of the total number of AB phantom image reviewers) required remediation.

Training

All of the ABs have phantom image review quality control activities that promote consistency among the various phantom image reviewers. Each AB conducts training sessions at which phantom image reviewers evaluate phantom images and discuss findings, including the application of AB phantom image review evaluation criteria.

3. Mammography Equipment Evaluation (MEE) and Medical Physicist Survey Report Reviews

The MQSA regulations state that ABs shall require every facility applying for accreditation to submit an MEE with its initial application and prior to accreditation to submit a medical physicist survey on each mammography unit at the facility (21 CFR 900.4(e)). All of the ABs have established FDA-approved policies and procedures for the review of both the MEE and the medical physicist survey report.

E. AB Onsite Visits to Facilities

The MQSA regulations (21 CFR 900.4(f)(1)(i)) require that each AB annually conduct onsite visits to at least five percent of the facilities the body accredits to monitor and assess facility compliance with the standards established by the body for accreditation. However, a minimum of five facilities shall be visited, and visits to no more than 50 facilities are required except in limited circumstances. During such visits, the AB is required to evaluate the following eight core elements:

- assessment of quality assurance activities;
- review of mammography reporting procedures;
- clinical image review;
- review of medical audit systems;
- verification of personnel duties;
- equipment verification;
- verification of consumer complaint mechanism; and
- other identified concerns.

At least 50 percent of the facilities visited shall be selected randomly and the other facilities visited shall be selected based on problems identified through state or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or other information in the possession of the AB, the MQSA inspectors, or the FDA (i.e., visits for cause).

ACR AB

In CY 2011, ACR accredited 8,129 facilities. It conducted 53 onsite visits (48 random, 5 for cause), thereby exceeding the minimum of 50 onsite visits required by regulation.

SAR AB

In CY 2011, SAR accredited 60 facilities. It conducted 5 onsite visits (all visits were random) thereby meeting the regulation requirement.

SIA AB

In CY 2011, SIA accredited 117 facilities. It conducted 30 onsite visits (all visits were random), thereby exceeding the minimum of 6 onsite visits required by regulation.

STX AB

In CY 2011, STX accredited 195 facilities. It conducted 13 onsite visits (10 random, 3 for cause), thereby exceeding the minimum of 10 onsite visits required by regulation.

F. Random Clinical Image Review (RCIR)

The MQSA regulations (21 CFR 900.4(f)(2)(i)) require that each AB annually conduct RCIRs of at least 3 percent of the facilities the body accredits to monitor and assess facility compliance with the standards established by the body for accreditation.

ACR AB

During CY 2011, ACR conducted 296 RCIRs (3.6 percent of the facilities it accredits), thereby exceeding the minimum of 244 RCIRs required by regulation.

SAR AB

SAR conducted 5 RCIRs (8.3 percent of the facilities it accredits) in CY 2011, thereby exceeding the minimum of 2 RCIRs required by regulation.

SIA AB

SIA conducted 32 RCIRs (27.4 percent of the facilities it accredits) in CY 2011, thereby exceeding the minimum of 4 RCIRs required by regulation.

STX AB

STX conducted 10 RCIRs (5.1 percent of the facilities it accredits) in CY 2011, thereby exceeding the minimum of 6 RCIRs required by regulation.

G. Additional Mammography Review (AMR)

If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility must provide clinical images and other relevant information, as specified by FDA (or a state certifying agency), for review by the facility's AB (21 CFR 900.12(j)). This AMR helps FDA (or a state certifying agency) determine whether there is a need to notify affected patients, their physicians, or the public that the quality of mammograms may have been compromised. The request for an AMR may also be initiated by an AB or a state certifying agency as long as the requirements in 21 CFR 900.12(j) and 21 CFR 900.22(f) are satisfied..

The following chart summarizes the number of AMRs conducted by each AB during CY 2011:

AB	Number of AMRs Conducted or Initiated*	Number Requiring Notification+	Number That Completed Notification
ACR	20	1	1
SAR	0	0	0
SIA	0	0	0
STX	2	0	0

*Note: STX has a contract with ACR to conduct its clinical image reviews during an AMR. The other three ABs have their own clinical image reviewers to evaluate their facilities' clinical images.

+Persons notified can include patients, their physicians, or the public.

H. Accreditation Revocation and Suspension

The MQSA regulations (21 CFR 900.3(b)(3)(iii)(I)) require that each AB have policies and procedures for suspending or revoking a facility's accreditation. If a facility cannot correct deficiencies to ensure compliance with the standards or if a facility is unwilling to take corrective actions, the AB shall immediately notify FDA and shall suspend or revoke the facility's accreditation. If a facility's accreditation is revoked by an accreditation body, FDA (or a state certifying agency) may conduct an investigation into the reasons for the revocation. Following such investigation, FDA (or a state certifying agency) may determine that the facility's certificate shall no longer be in effect or FDA (or a state certifying agency) may take whatever other action or combination of actions will best protect the public health.

During CY 2011, the ACR revoked the accreditation of three facilities.

I. Quantitative Accreditation and Inspection Information

As additional performance indicators, FDA analyzes quantitative accreditation and inspection information related to unit accreditation pass/fail data; reasons for denial of accreditation; and accredited facility performance during inspections.

1. Unit Accreditation Pass/Fail Data for CY 2011 Sorted by AB

	ACR	SAR	SIA	STX
Units Passed Accreditation	4,340 (99.8%)	20 (100%)	53 (100%)	83 (100%)
Units Denied Accreditation*	8 (0.2%)	0	0	0
Total	4,348	20	53	83

*Units that were still denied accreditation as of December 31, 2011.

At the conclusion of the reporting period, the accreditation pass rate of mammography units among the ABs ranged from 99.8 - 100 percent. The rates for units that were denied accreditation remained similar to those in the last reporting period.

2. Reasons for Mammography Unit Denial

In CY 2011, clinical image review failure and phantom image review failure were the reasons for denial of unit accreditation. Most of the facilities that receive a denial in the accreditation process complete a corrective action plan under the ABs' reinstatement protocols and successfully achieve the levels of quality needed for accreditation.

3. Facility Performance During Inspections Sorted by AB

In CY 2011, 83.1 percent of the accredited mammography facilities had no violations of the MQSA. This percentage is an increase from the percentage (82.2 percent) reported in 2010. Also, in CY 2011, only 0.5 percent of the facilities had a violation characterized as "most serious." This percentage is a decrease from the percentage (0.7 percent) reported in 2010. FDA actively works with these facilities on corrective measures, or takes regulatory measures if a facility cannot improve its performance.

There were no significant differences in average phantom image scores among the facilities accredited by the four ABs. Overall, average phantom image scores improved from those reported in the 2010 Report.

The average radiation dose (those measured by the facility medical physicists) for three ABs decreased from those previously reported and there was a non-significant increase for one AB. All ABs remain well below the dose limit of 300 millirads mandated by the MQSA final regulations.

The average processing speeds among the facilities of each AB remained similar to those previously reported and remain well within the range to produce satisfactory clinical images. The speed of film processing directly impacts the quality of mammograms.

	ACR	SAR	SIA	STX
Average Phantom Image Score*	13.4	13.1	13.1	13.4
Average Dose (in millirads)+	155.6	150.6	156.3	174.9
Average Processor Speed†	108.8	108.4	107.4	107.8

*The maximum possible phantom image score is 16. Four fibers, three masses, and three speck groups must be visible on the image for a minimum passing score.

+MQSA regulation requires that the dose not exceed 300 millirads.

†For standard cycle processing, 80 – 120 is considered normal processing speed.

VI. Status of the Action Items From the 2010 Report to Congress

In 2010, the STX AB conducted five RCIRs as opposed to the minimum of six RCIRs required by regulation. STX AB completed its action item (to make up the required RCIR) by conducting an additional RCIR in CY 2011.

VII. Conclusion

FDA's AB oversight program promotes collaboration and cooperation. Therefore, each AB, in concert with FDA, addresses any action items that may arise during the year. FDA and the ABs, working in partnership with the certified mammography facilities in the United States and with the states participating in inspection and other MQSA activities, are ensuring quality mammography across the nation.